DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01 D-02761

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision for Foods With Vinclozolin Residues

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the* **Federal Register].**

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision for Foods With Vinclozolin Residues Description

Under the pesticide tolerance reassessment process that the Environmental Protection Agency (EPA) was mandated to carry out under the Food Quality Protection Act of 1996 (FQPA), EPA has proposed to revoke the tolerances for the pesticide chemical vinclozolin on several food commodities. The FQPA includes a provision in section 408(l)(5) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346a(l)(5)), referred to as the "channels of trade provision," that addresses the circumstances under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical whose tolerance has been revoked, suspended, or modified by EPA.

In general, FDA anticipates that the party responsible for food found to contain vinclozolin residues (within the former tolerance) after the tolerance for the pesticide chemical has been revoked, will be able to demonstrate that such food was packed or processed during the acceptable timeframes cited in the draft guidance, by providing appropriate documentation to the agency as discussed in the draft guidance. FDA is not suggesting that firms maintain a certain set list of documents where anything less or different would likely be considered unacceptable. Rather, the agency is leaving it to each firm's discretion to maintain appropriate documentation to demonstrate that the food was so packed or processed.

Examples of documentation which FDA anticipates will serve this purpose consists of documentation associated with packing codes, batch records, and inventory records. These are types of documents that many food processors routinely generate as part of their basic food-production operations.

The likely respondents to this collection of information are firms in the produce and food-processing industries that handle food products that may contain residues of vinclozolin after the tolerances for this pesticide chemical have been revoked.

In the **Federal Register** of July 10, 2001 (66 FR 35990), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1 .-ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
307	1	307	3	921

'There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN'

No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
31	1	31	16	496

'There are no capital costs or operating and maintenance costs associated with this collection of information.

Estimates for the annual reporting burden were determined by using the maximum number of samples collected throughout a year that FDA believes might be found to contain vinclozolin residues. The estimated annual reporting burden was determined using the total number of samples historically tested for vinclozolin and the number of samples that historically contained vinclozolin residues. These numbers established a rate of samples expected to contain vinclozolin residues. This rate, when applied to the number of potentially affected establishments, was used to calculate the number of expected respondents.

When determining the estimated annual recordkeeping burden, FDA estimated that most firms (at least 90 percent) maintain (or maintain access to) documentation such as packing codes, batch records, and inventory records as part of their basic food production and/or import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of

firms which may not currently be maintaining this documentation to develop and maintain (or maintain access to) documentation such as batch records, inventory records, sales records, and distribution records.

Dated: 10/12/01

October 12, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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